

## REMARKS

The Applicant files with this response a substitute specification in compliance with 37 CFR 1.121(b)(3) and 1.125. Kindly replace the pending specification with the substitute specification enclosed with this correspondence. The substitute specification filed with this correspondence includes no new matter. A clean copy and a marked up copy are submitted.

This is intended as a full and complete response to the Office Action dated July 31, 2006, having a shortened statutory period for response set to expire on January 31, 2006. Claims 3, 15 to 18 have been cancelled (without prejudice). Claims 1, 4, 5, 6, 7, 12 to 14 have been amended and claims 19 to 21 have been added to clarify certain aspects of the invention. Applicant believes no new matter has been introduced by the amendments presented herein. The amendments have been made in a good faith effort to advance prosecution on the merits. Please reconsider the claims pending in the application for reasons discussed below.

### A. Objections to Specification

#### *Substitute Specification*

The Examiner noted that an Office letter was mailed on 10/27/03 requiring a substitute specification in compliance with 37 CFR, 1.121(b)(3) and 1.125. In response the Applicant filed a substitute specification on 12/23/03. The response however filed by the Applicant did not include two required statements (stating that the substitute specification would not include any new matter and that the substitute specification should replace the filed specification).

#### *Title of Invention*

The Examiner objected to the title of the invention as being not descriptive. The title of the invention has been amended.

#### *Trademarks*

The Examiner noted that trademarks are used in the application. Pages 36 and 37 of the application have been amended to identify the trademark OPENGENE as a trademark.

***Description***

The Examiner objected to the description on page 8 of Figure 1. Page 8 has been amended to further describe Figure 1. This amendment does not constitute new matter, it is merely from the figure 1 itself.

The Examiner noted a clerical error in the Specification; more specifically, the Examiner noted that the phrase “to diagnosis the disease” should be “to diagnose the disease”. Pages 3 and 4 have been amended to replace “diagnosis” in the phrase to “diagnose”.

**B. Claim Objections**

Claims 7 to 10 were objected to under 37 CFR 1.75 (c) as being in improper form; according to the Examiner, the claims are multiple dependant claims which depend on multiple dependant claims. Claim 7 has been amended and as a result, each of claims 7 to 10 amended, are not dependant on multiple dependant claims.

Claims 1, 6 and 12 were objected to for containing the phrase “to diagnosis the disease”. Each of claims 1, 6 and 12 have been amended; in the amended claims, the term “diagnosis” in the phrase “to diagnosis the disease” has been replaced with the term “diagnose”.

Claim 11 was objected to for depending from itself. Claim 11 has been amended and as amended, the claim does not depend from itself.

**C. Claim Rejections**

***Non-statutory Subject Matter***

Claims 1 to 6 and 11 to 14 were rejected for being directed to non-statutory subject matter. According to the Examiner, the claimed invention is a process of manipulating and converting data that does not transform an article or physical object to a different state or thing outside a computation device. The Examiner further contends that the claimed invention does not produce a useful, concrete and tangible result.

Each of independent claims 1, 4 and 12 have been amended. As amended, the invention claimed in independent claims 1, 4 and 12 produces a useful, concrete and tangible result. The claims dependent on the newly amended claims are similarly produce a useful, concrete and tangible result.

***Utility – 35 U.S.C. § 101***

Claims 1 to 6 and 11 to 14 were objected to under 35 USC 101. According to the Examiner, the claimed invention is not supported by a specific, substantial and credible utility or alternatively a well-established utility, and as a result the claimed invention lacks patentable utility. Each of independent claims 1, 4 and 12 have been amended.

***Utility – 35 U.S.C. § 112***

Claims 1 to 6 and 11 to 14 were rejected under 35 USC 112. According to the Examiner, the claimed invention is not supported by a specific, substantial and credible utility or alternatively a well-established utility, and as a result the claimed invention lacks patentable utility. The Examiner contends that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Independent claims 1, 4 and 12 have been amended.

Claim 2 was objected to on the basis that the phrase “the at least one strategy” lacks clear antecedent basis. Claim 2 has been amended.

Claim 4 in item d) was objected to on the basis that the phrase “the data” in the phrase “at least a portion of the data” lacks a clear antecedent basis.

Claim 4 in item d) was objected to on the basis that the phrase “the decision tree algorithms” lacks clear antecedent basis. Claim 4 has been amended.

Claim 6 was objected to on the basis that the phrase “the received data” lacks clear antecedent basis. Claim 6 has been amended and as amended, the phrase has a clear antecedent basis.

Claim 11 was objected to on the basis that it depends from itself and as a result, the phrases “the at least two strategies” and “the at least two medical diagnostic assays” lack antecedent basis. Claim 11 has been amended and as amended, the claim depends from claim 10.

Claim 13 was objected to on the basis that the phrase “the at least one strategy” lacks clear antecedent basis. Claim 13 has been amended and as amended the phrase has a clear antecedent basis.

***Anticipation – 35 U.S.C. § 102***

Claims 4 to 6 and claims 12 to 14 were rejected as being anticipated by Bapat et al. (Gut, Vol. 44, pages 698-703, 1999) (“Bapat”).

Bapat does not however disclose each feature of the present invention. The invention claimed is a method useful to optimize searches for genetic mutations. In contrast, Bapat uses a two-stage decision tree to compare alternative strategies for clinical diagnosis and management of colon cancer: (a) genetic analysis first, followed by clinical examinations, or (b) conventional clinical examination alone. Bapat presents evidence to support the hypothesis that there is a cost savings to be gained by incorporating genetic analysis in the clinical care of colorectal cancer patients. The authors of Bapat argue that the extra cost of genetic testing is more than offset by savings in clinical examinations safely avoided for individuals shown not to carry a hereditary predisposition. Bapat does not disclose a cost-effective method of identifying the unique genetic mutation(s) that leads to colon cancer, or any other genetic disease, but takes as given the cost of such analysis.

***Obviousness – 35 U.S.C. § 103***

Claims 1 to 3 were rejected as being unpatentable over Bapat. According to the Examiner, the claimed invention would have been obvious to a person of ordinary skill in the art at the time the invention was made over the process disclosed by Bapat. The Examiner contends that the process of Bapat could be interpreted as semi-automatic and that one of ordinary skill in the art would have been motivated to make it completely automatic by comprising instructions in the computer readable medium.

As discussed above under the heading entitled “Anticipation”, Bapat does not disclose every feature of the current invention. More specifically, Bapat does not disclose a method of determining a minimal cost test order for diagnosing mutations that relate to a disease.

***Other Amendments***

Claims 8, 9, 10, and 11 were amended to add a comma.

**Conclusion**

Having addressed all issues set out in the office action, Applicant respectfully submits that the claims are in condition for allowance and respectfully requests that the claims be allowed.

The Commissioner is authorized to appropriately charge or credit any fee that is due as a result of filing this paper to Deposit Account No. 14-1263, reference 101384-22, of Norris McLaughlin & Marcus, PA.

If the Examiner feels that a telephone conference would be helpful, please contact the undersigned at 212-808-0700.

**CONDITIONAL PETITION FOR EXTENSION OF TIME**

If entry and consideration to the amendments above requires an extension of time, Applicant respectfully requests that this be considered a petition therefore. The Assistant Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

**ADDITIONAL FEE**

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

Respectfully submitted,



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